

**Non-Technical Abstract**

Peripheral arterial disease (PAD) is a serious medical condition causing arterial insufficiency in up to 5% of men and 2.5% of women over 60 years of age. Individuals with severe disease often have few treatment options and suffer from significant disease-related morbidity, including amputation. The primary objective of this Phase I trial is to evaluate the safety and tolerability of VLTS-589 in subjects with PAD. VLTS-589 is a non-viral, plasmid-DNA gene transfer agent that encodes for the Developmentally-regulated Endothelial Locus-1 gene. In animal models that mimic poor circulation, VLTS-589 has been shown to stimulate the development of new blood vessels and improve exercise tolerance. VLTS-589 is administered by intramuscular (IM) injection into the diseased limb. Toxicology studies in rabbits indicate that both repeated IM and bolus IV administrations of VLTS-589 are without serious adverse effects.